

K013913

**510(k) Summary**

NOV 1 5 2002

**Submitter Information:**

PercuSurge, Inc.  
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**Trade Name:**

PercuSurge GuardWire Temporary Occlusion and  
Aspiration System

**Common Name:**

Distal Occlusion Balloon Catheter

**Classification Name:**

Catheter, Intravascular Occluding, Temporary

**Premarket Notification Number:** K013913

**Predicate Device:**

3-6 GuardWire Plus™ System

**Date Prepared:**

October 31, 2002

<i>PercuSurge, Incorporated</i> Sunnyvale, California	PercuSurge GuardWire System for Use in the Percutaneous Interventional Treatment of Saphenous Vein Bypass Grafts
<b>Premarket Notification [510(k)] Application</b>	October 31, 2002

### Description

The PercuSurge GuardWire Plus Temporary Occlusion & Aspiration System provides temporary vascular occlusion during diagnostic and interventional procedures in the coronary vasculature, specifically-diseased coronary bypass grafts. It is comprised of four principal components: the GuardWire Temporary Occlusion Catheter, the MicroSeal Adapter, the EZ Flator Inflation Device and the Export Aspiration Catheter.

The GuardWire Plus System is a sterile, single-use disposable device, packaged in a protective polyethylene tray covered by a polyethylene/Tyvek pouch. The pouch is then placed into a chipboard carton for protection during shipment. Both the pouch and the carton are labeled for easy product recognition.

The GuardWire Plus System is available in the following configurations:

Table 1: GuardWire Plus Configurations

Catalog Number	Wire Diameter	Wire Length	Balloon Range
G14-5-200US	0.014"	200cm	2.5 – 5.0mm
G14-5-300US	0.014"	300cm	2.5 – 5.0mm

The GuardWire Plus Temporary Occlusion Catheter is a 0.014" diameter guidewire available in lengths of 200 and 300 centimeters. The industry standard 0.014" diameter of this device allows for the delivery of a wide range of diagnostic and interventional devices over its shaft. The shaft is coated to limit the frictional forces encountered when passing therapy devices over the wire. The distal end of the GuardWire contains an inflatable elastomeric balloon designed to occlude the target vessel during emboli-causing procedures such as stenting or angioplasty. The balloon is fully compliant and exerts less than two atmospheres of pressure on the target vessel during occlusion. The distal tip of the wire is a shapeable radiopaque coil similar to other standard guidewires.

The GuardWire is used in conjunction with a removable adapter that assists in the inflation and deflation of the distal occlusion balloon. The MicroSeal Adapter provides a means for opening and closing the internal MicroSeal of the GuardWire which is a small valve internal to the GuardWire Plus Temporary Occlusion Catheter. When the MicroSeal Adapter is in the "OPEN" position, the GuardWire internal seal is opened. This establishes fluid access to the occlusion balloon through the hollow GuardWire shaft. When the MicroSeal Adapter is in the "CLOSE MICROSEAL" position, the MicroSeal of the GuardWire closes. This discontinues fluid access to the occlusion balloon. This allows the occlusion balloon of the GuardWire to remain inflated in the absence of direct communication with an inflation device.

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### GuardWire Plus catheter

The proximal end of the GuardWire Plus catheter is able to control the flow of contrast fluid when used in conjunction with the MicroSeal Adapter. This is achieved by means of a micro-seal plug located on the proximal end of the GuardWire Plus catheter. The MicroSeal plug consists of a wire that is formed to provide friction in the hypo-tube with a sealing member on the distal end. The plug is pushed in and out, hence the sealing member moves distal and proximal to the inflation port, via the MicroSeal Adapter pads that grip the wire plug and are moved in conjunction with the Adapter knob. An inflation port is positioned on the hypotube to line up with the inflation port on the Adapter to provide a continuous fluid path to inflate the occlusion balloon. Fluid is transferred from the EZ Flator to the Adapter through the hypo-tube to fill the occlusion balloon. Fluid, i.e., diluted contrast, passes through the distal end and into the elastomeric occlusion balloon via the laser coil.

### EZ Flator Inflation Device

The EZ Flator is a controlled volume syringe system contained in a single housing that enables the exact amount of diluted contrast to fill the occlusion balloon to the appropriate size. The fluid is pushed through the extension tubing via a steel plunger pin that is controlled by the inflation dial. Once the hypo-tube is prepped and the pin is pushed past the distal o-ring, a seal is formed in the extension line. The volume of the plunger pin in the inflation syringe barrel distal to the distal o-ring equates to the volume of the balloon. Therefore, inflation of the balloon is achieved by turning the dial, which pushes the plunger pin forward, to the appropriate volume indicated on the dial pad.

The deflation syringe barrel is used for prepping the hypo-tube and deflating the occlusion balloon. A handle is attached to the plunger to provide a vacuum to the deflation syringe barrel. The deflation syringe barrel is used only when the inflation dial is in the "0" position, i.e., when the plunger pin is positioned proximal to the distal o-ring, as shown below, thereby opening the fluid path. In the drawing below the housing and plunger handle are not shown.

### Export Aspiration catheter

The Export Aspiration catheter is a dual lumen catheter. The smaller of the lumens is the wire lumen used to run over the GuardWire. The size of the wire lumen is sized so that the Export catheter may run over the GuardWire smoothly. The larger sized lumen is the aspiration lumen. Via the 20cc syringe and one-way stopcock attached to the proximal end of the Export, blood and debris is evacuated from the graft and into the syringe.

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### **MicroSeal Adapter**

The MicroSeal Adapter provides the mechanism to move the plug on the GuardWire catheter. Six grip pads are located on the Adapter, three on the upper half and three on the lower. Three wire clips are found on the lower half and are used for holding the wire firmly between the pads. The proximal pads are movable via the Adapter knob. The other four pads are immovable and are used to hold in place the GuardWire distal to the plug. Once the wire is placed in the Adapter and the knob is moved to the open position, the proximal pads slide, opening the plug. Diluted contrast flows through the Adapter via the inflation port. This port is sealed when the Adapter is closed and is lined up with the inflation port on the GuardWire when placed in the Adapter.

### **Statement of Indications for Use**

The PercuSurge GuardWire Plus Temporary Occlusion & Aspiration System is indicated for use in the coronary saphenous vein bypass grafts (2.5-5.0mm) to:

- Contain and aspirate embolic material (thrombus/debris) while performing percutaneous transluminal coronary angioplasty or stenting procedures.
- To subselectively infuse/deliver diagnostic or therapeutic agents with or without vessel occlusion.
- The safety and effectiveness of this device as an embolic protection system has not been established in the cerebral, carotid or peripheral vasculature.
- The safety and effectiveness of the device as an embolic protection system has not been established in treating patients with acute myocardial infarction.
- The safety and effectiveness of the device as an embolic protection system has not been established in treating native coronaries.

### **Technological Characteristics**

The technological characteristics of the GuardWire 2.5-5.0 Temporary Occlusion and Aspiration System are substantially equivalent in materials of construction and methods of manufacture as the predicate device the GuardWire 3-6 Temporary Occlusion and Aspiration System. The performance of both systems, the 2.5-5.0 and the 3-6, has been assessed using similar bench test methods and under in-vitro simulated use conditions and determined to be equivalent.

### **Clinical Performance Data (SAFER Study Data Results Summary)**

The data below illustrate the vessel sizes treated in the SAFER study (IDE G980209, and cleared under 510(k) K003992). Table 1 demonstrates that out of 406 GuardWire patients, (417 vessels and 442 lesions) 113 lesions treated were sized at 3.0mm or

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less. Table 2 further analyzes the data demonstrating the safety and efficacy results (MACE) for this patient population (n=111 patients).

Table 1: RVD in GuardWire™ Patients

<b>Reference Vessel Diameter (RVD, in mm)</b>	<b>GuardWire™ (N=406 Patients, N=442 Lesions)</b>
0 mm ≤ RVD < 2.5 mm	7.4% (31 /417)
2.5 mm ≤ RVD < 3.0 mm	19.7% (82 /417)
3.0 mm ≤ RVD < 3.5 mm	30.0% (125 /417)
3.5 mm ≤ RVD < 4.0 mm	24.2% (101 /417)
4.0 mm ≤ RVD < 4.5 mm	10.3% (43 /417)
4.5 mm ≤ RVD < 5.0 mm	5.5% (23 /417)
RVD ≥ 5.0 mm	2.9% (12 /417)

All data are from QCA.

Denominator = # of vessels (n=417)

Table 2: MACE Rate in Reference Vessel Diameters < 3mm

<b>Non-Hierarchical Complications (to 30 Days)</b>	<b>RVD &lt; 3 mm (N=111 Patients)</b>
MACE (Death, MI, Emergent CABG, TVR)	8.1% (9 /111)
Death	0.0% (0 / 111)
Myocardial Infarction (Q wave or non-Q wave)	8.1% (9 / 111)
Q-Wave MI	0.0% (0 / 111)
Non-Q-Wave MI	8.1% (9 / 111)
Emergent CABG	0.0% (0 / 111)
Target Lesion Revascularization	1.8% (2 / 111)
TL-CABG	0.0% (0 / 111)
TL-PTCA	1.8% (2 / 111)
Target Vessel Revascularization not involving the Target Lesion	0.9% (1 / 111)
TV/non-TL-CABG	0.0% (0 / 111)
TV/non-TL-PTCA	0.9% (1 / 111)

Patients who had multiple lesions treated and had at least one RVD <3mm are included in this analysis.

Denominator = #of patients

## Conclusion

The 2.5-5.0mm GuardWire Plus Temporary Occlusion and Aspiration System is substantially equivalent to the predicate device in materials of construction, methods of manufacture, performance and intended use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

NOV 15 2002

Mr. Matthew Moon  
Manager, Regulatory Affairs  
540 Oakmead Parkway  
Sunnyvale, CA 94085

Re: K013913

Trade/Device Name: PercuSurge GuardWire Plus Temporary Occlusion and Aspiration System

Regulation Number: 21 CFR 870.1250

Regulation Name: Catheter, Percutaneous

Regulatory Class: Class II

Product Code: NFA

Dated: August 13, 2002

Received: August 19, 2002

Dear Mr. Moon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

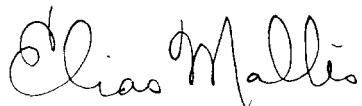
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Mr. Matthew Moon

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-\_\_\_. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address  
<http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

  
for

Bram D. Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number: K013913

Device Name: Export Aspiration Catheter

Indications for Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓  
(Per 21 CFR 801.109)

OR

Over-The-Counter \_\_\_\_\_

(Optional Format 1-2-96)

*Ashley B. Brans*  
Division of Cardiovascular & Respiratory Devices  
510(k) Number K013913